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| 10/541,949 | 06/07/2006 | Magne Solbakken | PN0302 | 6745 |

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| EXAMINER | |
|---|---|
| SCHLIENTZ, LEAH H | |

| ART UNIT | PAPER NUMBER |
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| 1618 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/541,949 | SOLBAKKEN ET AL. | |
| | Examiner | Art Unit | |
| | Leah Schlientz | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 4 of U.S. Patent No. 6,264,914. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject.

Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 10 of U.S. Patent No. 6,921,525. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject.

Claims 1 – 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5 of U.S. Patent No. 7,182,934. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R wherein V is an organic group having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety. The reporter moiety includes radionuclides conjugated to a chelating ligand; the linkers include amino acids; and the compounds are used for methods of imaging a human or animal subject.

Claims 1 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 11 of copending Application No. 10/559,880. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both sets of claims are drawn to compositions of formula V-L-R, or V-L-Z, wherein V is a vector having binding affinity for an angiotensin II receptor, L is a linker moiety, and R is a reporter moiety, as in the instant case, or Z is a chelating agent carrying an imaging moiety, as in the '949 application. Both sets of claims teach the same chelators, the imaging moiety may be a radionuclide, and the compounds are used for methods of generating images of a human or animal body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 101*

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e. results in a claim which is not a proper process under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 –10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a compound of formula 1, wherein V is a non-peptidic vector having affinity for the angiotensin II receptor. However, the metes and bounds of the claims are unclear as to what types of structures are to be encompassed by such a functional description. For example, the specification defines a few specific examples of imidazole Ang II antagonist ligands including losartan, valsartan, candesartn and eprosartan (paragraph 0019), but it is unclear from such a limited disclosure of a few specific examples what other structures out of any and all possible "non-peptidic vectors" would be capable of having angiotensin II receptor binding affinity. As such, the metes and bounds of the claims are not clearly set forth and the scope of the invention cannot be distinctly ascertained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Klaveness *et al.* (US 6,264,914).

Klaveness discloses compositions of the formula V-L-R, where V is an organic group having binding affinity for an angiotensin II receptor site, L is a linker moiety, and R is a moiety detectable in *in vivo* imaging of a human or animal body (abstract). The composition may be used to image cardiovascular diseases and disorders. Losartan is a preferred vector (column 2, line 67; column 3, line 17). Most commonly, the linker comprises two or more reactive moieties connected by a spacer element (column 13, lines 18 – 20). The spacer may be include polyamino acids, homo- and co-polymers of lysine, glutamic acid and aspartic acid, and polypeptides (column 14, lines 21 – 23). See also column 19, lines 39 – 45. The reporter groups include metal radionuclides, such as 90Y, 99mTc, etc. chelated by chelant groups on the linker moiety (column 23, line 55 – column 25). An exemplified compound is a Tc chelate of N-(N-MAG-3-glycyl)-Losartan (claim 3, compound v).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness *et al.* (US 6,264,914) in view of Cuthbertson *et al.* (WO 03/006491).

Klaveness discloses compositions of the formula V-L-R, where V is an organic group having binding affinity for an angiotensin II receptor site, L is a linker moiety, and R is a moiety detectable in *in vivo* imaging of a human or animal body (abstract), as set forth above. A variety of chelating moieties may be used to chelate a radionuclide as the reporter moiety, R (see column 24 – 25).

Klaveness teaches that a variety of chelating agents are suitable to bind the radionuclude, but does not specifically teach chelating agents of formula II as claimed in claims 3 and 4.

Cuthbertson discloses chelating agents of formula III, shown on page 9, or preferably formula e on page 10. Such chelating agents may be radiolablelled (see page 11, first paragraph), including binding metal ions such as $^{90}Y$, $^{99m}Tc$, etc. (page 23, liens 10 – 13).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the diaminedioxime chelators taught by Cuthbertson as the chelating agent employed in the V-L-R compounds taught by Klaveness. Klaveness teaches that a variety of chelating agents may be employed to bind a radionuclide. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because the diaminedioxime chelators are taught in the prior art to be functional equivalents for use in binding radionuclides, as shown by Cuthbertson.

### *Claim Objections*

Claim 1 is objected to because of the following informalities: the claim contains a minor typographical error, wherein "non-peotidic" appears rather than "non-peptidic." Appropriate correction is required.

### *Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER